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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,883	09/19/2003	Chong-Sheng Yuan	466992001100	6779
25225	7590	02/02/2006	EXAMINER	
MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/665,883	Applicant(s) YUAN, CHONG-SHENG	
	Examiner Charles L. Patterson, Jr.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2004 and 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
 4a) Of the above claim(s) 1-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicants' election with traverse of Group IV, claims 50-72 in the reply filed on 12/27/05 is acknowledged. The traversal is on the ground(s) that Groups III and IV are in the same class and subclass and there would be no undue search burden. After further consideration the examiner will examine Groups III and IV, claims 31-72. It is noted that applicant characterize Group IV as claims 50-77, but apparently it should be claims 50-72 as there are only 72 claims present in the application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/27/06.

The disclosure is objected to because of the following informalities:

On page 27, line 6, the recitation of "lithium" is apparently incorrect. This example is dealing with sodium detection and therefore the instant recitation should apparently be "sodium".

The recitation of "Toluidin" at the end of the legend to Table 6 is apparently incorrect. Apparently the correct recitation should be "Toluidine" as in Table 3 and claims 44, 47, 67 and 71.

Appropriate correction is required.

Claims 35, 43, 49, 56 and 66 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to the claims in the alternative only. See MPEP § 608.01(n).

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Claims 35-36, 43, 45, 47, 49-50, 56-57, 60, 66, 69 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35, 43, 49, 56 and 66 are confusing because the claims are dependent upon a non-elected claim.

Claims 36 and 57 are confusing because the arrow does not extend the full length of the term above the arrow. Parts of the term above the arrow might be construed as belonging to the words below it.

Claim 45 is confusing and apparently incorrect in the recitation of "kit of" on line 1, which should apparently be "kit for".

Claims 47 and 71 are confusing in the recitation of "if sodium [lithium] ions are not present". Apparently the specification teaches that the amount of sodium [or lithium] ions present can be determined from the reaction scheme in Tables 3 and 6, and therefore sodium [or lithium] ions are apparently present if product is formed, just a decreasing amount of product is formed with increasing sodium [or lithium].

Claim 50 is confusing in the recitation of "(b)" in line 6. Apparently the correct recitation should be "(a)".

Claim 60 is confusing in the recitation of "a adenosine 3',5'-bisphosphate" in lines 3-4. This instant recitation infers that there is more than one adenosine 3',5'-bisphosphate and furthermore the instant recitation should be "an adenosine 3',5'-bisphosphate". Apparently the "a" should be left out as was done in claim 39.

Claim 69 is incorrect in the recitation of "futher", which should apparently be "further".

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To begin with, the recitation of "Intra-assay", "Inter-assay" and "CV%" in Table 4 and Table 7 is not understood. What do these terms refer to?

The instant claims are drawn to "contacting the sample with a sodium-sensitive [or lithium-sensitive] 3' (2'), 5'-bisphosphate nucleotidase". The specification does not teach which 3' (2'), 5'-bisphosphate nucleotidases are sodium-sensitive and which are lithium-sensitive. Without such a teaching one of ordinary skill in the art would be unable to perform the claimed methods. The specification states that "any suitable 3' (2'), 5'-bisphosphate nucleotidase can be used" (paragraph 66 and 91) and gives as examples SEQ ID NO:4 and 5 in each paragraph. The specification does not state which 3' (2'), 5'-bisphosphate nucleotidases are sensitive to sodium and which ones are sensitive to lithium. Presumably the enzymes of both SEQ ID NO:4 and 5 cannot be sensitive to both or else the assay could not distinguish sodium from lithium.

Apparently the specification teaches the use of a 3' (2'), 5'-bisphosphate nucleotidase that is sensitive to either sodium or lithium to distinguish sodium or lithium ions in the sample. This is done by first making a calibration curve with low and high concentrations of the two ions and then

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seeing where on the calibration curve the unknown sample falls. It is not seen how the chimeric protein containing a leader sequence fits into this. Is the purpose of this simply to provide a stable enzyme by including a leader sequence?

It is maintained that one of ordinary skill in the art could not practice the claimed invention without undue experimentation.

No art rejection is being made. The examiner could find nothing in the prior art that would anticipate or make obvious the claimed invention.

Lopez-Coronado, et al. (U) and Lurganov, et al. (V) are cited as of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

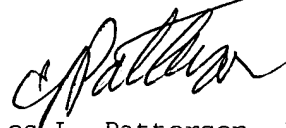
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Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
January 27, 2006